COVID-19 Vaccine Early Distribution
Vaccine Development & Authorization Process

Overview

- The U.S. Food and Drug Administration (FDA) ensures the safety, effectiveness, and availability of vaccines in the United States.
- When a public health emergency occurs – such as the COVID-19 pandemic – the FDA can issue an Emergency Use Authorization (EUA) to provide more timely access to critical medical products, such as vaccines.
- The Centers for Disease Control and Prevention (CDC) make specific vaccination recommendations for the United States based on input from the Advisory Committee on Immunization Practices (ACIP), an independent group of medical and public health experts who develop recommendations on vaccines. ACIP will review FDA authorizations and approvals and make recommendations based on principles that maximize benefit to Americans.
- Operation Warp Speed is working to develop, test, manufacture, and deliver safe and effective COVID-19 vaccines using CDC and FDA processes.

Key Takeaway: COVID-19 vaccines are being authorized under the U.S. Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), which provides for an expedited review of vaccines and medications during emergencies, such as a pandemic. An EUA includes the same steps taken in full-term clinical trials, only with a consolidated timeline. Multiple federal agencies are working together to ensure that COVID-19 vaccines meet FDA's standards and are safe and effective for the American public.

Key Points About the Emergency Use Authorization Process

- FDA reviews evidence as it becomes available across the phases of clinical trials to evaluate vaccine development progress. This approach allows for an expedited approval process.
- After an EUA, CDC's Advisory Committee on Immunization Practices (ACIP) reviews available data before making a recommendation whether and how to use the vaccine.
- The FDA and CDC have pledged to follow rigorous review processes to ensure vaccine safety and effectiveness. They carefully balance any known or potential risks of making vaccines available during an emergency with any known or potential benefits to the public.

Phased Clinical Trial Process

- For FDA to authorize a vaccine, it must undergo a strict three-phase process of research development:
  - **Phase I:** Small groups of healthy people receive the vaccine to assess safety and the immune response.
  - **Phase II:** Hundreds of people receive the trial vaccine to confirm a desired immune response and examine safety.
  - **Phase III:** Thousands of people receive either the trial vaccine or an inactive placebo to determine the vaccine's effectiveness in preventing infection as well as safety.

What You Can Do Now to Prepare

- Visit the VA COVID-19 Vaccine SharePoint Site for more information on VA's preparations for a COVID-19 vaccine.
- Visit the COVID-19 Resource Room to submit your vaccine questions.

Resources

- Learn more about how CDC is making COVID-19 vaccine recommendations
- CDC's Testing and Approval Process
- FDA's COVID-19 Vaccines and the EUA process
- Operation Warp Speed

From Research to Vaccination

Operation Warp Speed's processes and timelines ensure vaccine effectiveness and patient safety. Safety is a top priority for all federal partners as they work to make COVID-19 vaccines available.

Operation Warp Speed (OWS) is a partnership between the Department of Health and Human Services (HHS) – which includes the FDA and CDC – and the Department of Defense (DoD). VA, along with other federal and private sector organizations, such as universities and pharmaceutical companies, is working with OWS to develop, test, manufacture, and deliver 300 million doses of safe and effective vaccines by building upon FDA's EUA and CDC's ACIP processes for reviewing, authorizing, and recommending vaccines.

OWS' COVID-19 vaccine development process, shown below, allows for vaccines to be delivered to patients rapidly while adhering to strict standards for safety and effectiveness:

Activities/Phases	Operation Warp Speed Timeline	Key Processes
These two processes, typically performed separately, are performed concurrently: • Research and Development identifies preclinical trial vaccine candidate(s) • Phase I Clinical Trials	5 months	• Technological breakthroughs in science have enabled scientists to examine and understand the DNA of the virus in days instead of years. • Researchers used vaccine platforms developed for other diseases.
These three processes, typically performed separately, are performed concurrently: • Phase II Clinical Trials • Phase III Clinical Trials • Manufacturing	6 months	• Large scale Phase III clinical trials of 30,000 volunteers allow for rapid collection and analysis of safety and effectiveness data of demographically diverse populations. • Two promising candidates began Phase III clinical trials in July 2020, with other vaccines following. Before beginning Phase III, candidates must show safety data and promising immune effects from earlier phases.
Manufacturing	9 months (occurring during Phase II and Phase III Clinical Trials)	• The U.S. Government funds manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available upon FDA EUA or final approval.
Distribution	3 months	• CDC leads distribution planning with DoD support. • Planning for infrastructure and distribution begins before vaccines are approved or authorized.

Working Continuously to Ensure Safety and Effectiveness

Even after FDA authorizes and approves a vaccine for use, ongoing monitoring of safety and effectiveness data continues. Vaccine safety monitoring systems are put in place to identify any adverse reactions. This continued monitoring can pick up on possible safety risks that may not have been seen in clinical trials.